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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,360	03/16/2001	Masato Horie	Q 63396	7873

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EXAMINER
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CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

8

DATE MAILED: 12/13/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/787,360

Applicant(s)

HORIE ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19-23 is/are pending in the application.
- 4a) Of the above claim(s) 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other:  |

## DETAILED ACTION

### *Election/Restrictions*

1. Claims 1-18 have been cancelled as requested in the amendment of Paper No.7.
2. Applicant's election without traverse of Group III, claim 9 and election of species of physiological activity as brain memory-forming activity in Paper No. 7 is acknowledged.

Claim 19 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

3. Claims 20-23 (claims 19-22 as presented by Applicant and renumbered according to 37CFR Rule 126) have been added as requested in the amendment of Paper No.7.

Claims 20-23 are under examination in the instant office action.

### *Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 20-23 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant application has provided a description of an antibody to a protein encoded by an isolated DNA. However, the instant application does not disclose the biological role of this protein or its significance.

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It is clear from the instant application that the protein of SEQ ID NO:1, encoded by nucleotide sequence of SEQ ID NO:2 or LY6H gene described therein is what is termed an “orphan protein” in the art. The DNA of the instant application has been isolated because of its similarity to a known DNA. There is little doubt that, after complete characterization, this DNA, encoded protein and antibodies to the protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant’s claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are “useful” as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediate obvious or fully disclosed “real world” utility. The court held that:

“The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility”, “[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field”, and “a patent is not a hunting license”, “[i]t is not a reward for the search, but compensation for its successful conclusion”.

The instant claims are drawn to antibodies, which bind specifically to a protein encoded by a newly isolated LY6H gene. However, the instant specification fails to describe function or biological significance of the protein and, consequently, credible, substantial and specific utility

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of the claimed antibodies. It is clear from the instant application that the novel protein described thereby belongs to Ly6 family of proteins. It has been suggested in the literature that this group of proteins “have been identified as a class of cell surface glycoproteins forming a gene cluster on mouse chromosome 15”. “The Ly6 family is specifically expressed at high levels in bone marrow cells and lymphoid cells and, therefore, has been utilized as a marker for T-cell differentiation and hematopoietic stem cells (see page 1, lines 19-25 and page 2, line 1 of the instant specification). It is stated further that “elucidation of the physiological roles played by such proteins of the Ly6 family and the genes coding for the proteins and the resulting information are considered to be of use in the field of fundamental scientific research as well as in the pharmaceutical field in connection with the purification of blood stem cells, studies on the differentiation of blood cells, activation of immune cells, inhibition of activation of immune cells, therapy of tumors and the like” (see page 2, lines 6-14). Thus, the importance of the Ly6 family of proteins has been described in the art. However, the instant specification fails to describe the biological function and importance of the newly discovered LY6H gene or its expression product. In the absence of knowledge of the biological significance of this specific LY6H DNA and encoded LY6H protein, there is no immediately obvious patentable use for the polynucleotide or the encoded protein. Similarly, in the absence of knowledge of biological significance of the LY6H protein there is no immediately obvious patentable use for the antibodies to the novel protein. The similarity or homology of the disclosed DNA to DNA of mouse Ly6 family does not make the instant DNA or encoded protein of the same biological significance as mouse Ly6 DNA. The instant specification asserts that “the expression product (polypeptide) of the invention, thus provided, enables provision of a drug for prophylaxis and

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therapy of neurodegenerative diseases such as Alzheimer's disease, Alzheimer's type dementia, Parkinson's disease and ischemic brain" (page 9, lines 7-11). However, there is no evidence of record, which associates the instant DNA or encoded protein with any diseases or disorder. The working example 2 on page 101 provides controversial information about expression of LY6H protein in the brain of one patient with Alzheimer's disease. Based on the provided information (see Figure 1) it is impossible to conclude that LY6H protein might have any specific significance associated with Alzheimer's disease. Thus, the instant application fails to demonstrate use of the antibodies to LY6H protein as a marker for any disease or condition, which would be a real world use. To employ the antibodies of the claimed invention in any future methods is not a real world because it would eventually relate to a protein for which no biological function is known. Because the instant specification does not teach a biological activity of the protein, one cannot prevent or treat a condition or disease as implied by the specification and, consequently one cannot find a specific, credible and substantial utility for the antibodies to a protein of unknown function. To employ antibodies of the instant invention in any of the disclosed methods would clearly be using them as the object of further research, which has been determined by the courts to be a utility, which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for the claimed antibodies then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claims 20-23 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established

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utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 23 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 23 is a newly added claim. The claim is directed to an antibody which binds specifically to an expression product expressed by a host cell comprising an expression vector comprising a DNA molecule comprising the nucleotide sequence of SEQ ID NO:3, operably linked to a promoter, or a DNA molecule comprising a nucleotide sequence which hybridizes under stringent conditions to the nucleotide sequence of SEQ ID NO:3, operably linked to a promoter. However, the instant specification fails to describe antibodies, which are encompassed by these claims. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of an antibody which binds specifically to a protein of SEQ ID NO:1. The subject matter, which is claimed is described above. First, a

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determination of the level of predictability in the art must be made in that whether the level of skill in the art leads to a predictability of structure; and/or whether teachings in the application or prior art lead to a predictability of structure. The claim is an antibody which binds specifically to an expression product expressed by a host cell comprising an expression vector comprising a DNA molecule comprising the nucleotide sequence of SEQ ID NO:3, operably linked to a promoter, or a DNA molecule comprising a nucleotide sequence which hybridizes under stringent conditions to the nucleotide sequence of SEQ ID NO:3, operably linked to a promoter. First, the claims are not limited to an antibody to a protein with a specific amino acid sequence. The claims only require the antibody to bind to a certain expression product. The specification only describes a protein having the amino acid sequence of SEQ ID NO:1 and an antibody to this particular protein and fails to teach or describe any other antibodies, which bind to proteins that lack the amino acid sequence of SEQ ID NO:1. Therefore, there is a lack of guidance or teaching regarding structure and function because there is only a single description provided in the specification and because there is no guidance found in the prior art.

Next in making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, each claimed species and genus must be evaluated to determine whether there is sufficient written description to inform a skilled artisan that applicant was in possession of the claimed invention at the time the application was filed. With this regard, the instant application fails to provide a written description of the species or the genus which are encompassed by the instant claims except for the antibody to a protein of SEQ ID NO:1. The specification does not provide a complete description of those antibodies that bind specifically to an expression product expressed by a host cell comprising an expression

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vector comprising a DNA molecule comprising the nucleotide sequence of SEQ ID NO:3, operably linked to a promoter, or a DNA molecule comprising a nucleotide sequence which hybridizes under stringent conditions to the nucleotide sequence of SEQ ID NO:3, operably linked to a promoter. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. The specification fails to provide a representative number of species for the claimed genus (those antibodies which bind specifically to an expression product expressed by a host cell comprising an expression vector comprising a DNA molecule comprising the nucleotide sequence of SEQ ID NO:3, operably linked to a promoter, or a DNA molecule comprising a nucleotide sequence which hybridizes under stringent conditions to the nucleotide sequence of SEQ ID NO:3, operably linked to a promoter) because the specification teaches only the one embodiment of an antibody to a protein of SEQ ID NO:1. Therefore, the claims are directed subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 is indefinite for recitation of "stringent hybridization conditions". Claim 23 is directed to an antibody which binds specifically to an expression product expressed by a host cell comprising an expression vector comprising a DNA molecule comprising the nucleotide sequence of SEQ ID NO:3, operably linked to a promoter, or a DNA molecule comprising a nucleotide sequence which hybridizes under stringent conditions to the nucleotide sequence of SEQ ID NO:3, operably linked to a promoter polynucleotide, which hybridizes under stringent conditions. However, the metes and bounds of "stringent hybridization conditions" cannot be determined from the claim. There are a multitude of conditions that are used by the skilled artisan, which could be considered, which range from low stringency to high stringency, all of which depend on a number of variables in the hybridization process. Without knowing which set of conditions is intended by the claim, one would not be able to determine the metes and bounds of the claim. Should Applicant include specific conditions for stringent hybridization the rejection could be avoided.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Armstrong et al. (1983).

Claim 21 is directed to an antibody which binds specifically to a protein of SEQ ID NO:1 having at least one deletion, addition and/or substitution mutation in said amino acid sequence. The claim does not provide specific amino acid sequence of the protein; therefore, the only limitation of the claim is that the protein must exhibit brain memory-forming activity. Thus, an antibody to any protein, which is related to brain memory-forming activity, would be anticipated by the claim. Armstrong et al. teach monoclonal antibodies to choline acetyltransferase (ChAT). It is well known in the art that acetylcholine is a major neurotransmitter, which is associated with brain cognitive function. ChAT is an enzyme responsible for the synthesis of acetylcholine, and, consequently, a protein associated with physiological activity as brain memory-forming activity, thus, meeting the limitation of claim 21.

### *Conclusion*

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-0294 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.  
December 12, 2001

*oe*

CHRISTINE J. SAOUD  
PRIMARY EXAMINER

*Christine J. Saoud*